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To: Hospitals HOSP 27

From: Susan Schroeder, Director
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HCFA Hospital Condition of Participation: Patients' Rights

Attached is a copy of the Condition of Participation: Patients' Rights that became effective for all hospitals participating in the Medicare program on August 2, 1999. This Condition of Participation is found in the Code of Federal Regulations at 42 CFR 482.13. The Health Care Financing Administration (HCFA) information on the background of this regulation and responses to comments made prior to July 2, 1999 can be found at the website:

http://www.access.gpo.gov/su_docs/aces/aces140.html

The Wisconsin Bureau of Quality Assurance (BQA) has requested Interpretive Guidelines, and made suggestions to HCFA about questions that need clarification. BQA will forward to hospitals any clarifying information as soon as we receive it.

In the absence of Interpretive Guidelines, hospitals are advised to familiarize themselves with the regulation and to attempt in good faith to comply with the regulation.

At 42 CFR 482.13(e), under the standard for restraint for acute medical and surgical care, the regulation refers to "other licensed independent practitioner permitted by the State and hospital to order a restraint." In Wisconsin, the only independent practitioner besides a physician who may be credentialed by a hospital to order restraints for acute medical and surgical care is an Advanced Practice Nurse Prescriber, that is, an advanced practice nurse who has been granted a certificate to issue prescription orders under Wisconsin State Statutes, Section 441.16(2).

At 42 CFR 482.13(f)(3)(ii)(C), under the standard for seclusion and restraint for behavior management, the regulation permits seclusion or restraint only "in accordance with the order of a physician or other licensed independent practitioner permitted by the State and hospital to order seclusion or restraint." In Wisconsin, only certain physicians may order restraints for persons receiving inpatient hospital services for mental illness, developmental disabilities, alcoholism or drug dependency. Only certain physicians

and licensed psychologists may order seclusion. Under Wisconsin State Statutes, Section 51.61(1)(i):

> The treatment director shall specifically designate physicians who are authorized to order isolation or restraint, and shall specifically designate licensed psychologists who are authorized to order isolation. In the instance where the treatment director is not a physician, the medical director shall make the designation.

At 42 CFR 482.13(f)(3)(ii)(C), the standard for seclusion and restraint for behavior management requires that "[a] physician or other licensed independent practitioner must see and evaluate the need for restraint or seclusion within 1 hour after the initiation of this intervention." Wis. Stats. s. 51.61 only limits the classes of providers who may order restraint or seclusion, not those who may "evaluate the need for restraint or seclusion." Accordingly, in Wisconsin a face-to-face evaluation by an advanced practice nurse prescriber would satisfy this requirement, in light of the statutory authority of advanced practice nurse prescribers to "issue prescription order" for certain "devices…[I]ntended to affect the structure or function of the body of persons…" Sections 441.16 and 450.01(6)(c ), Wis.Stats. The requirement for evaluation within 1 hour after initiation of restraint or seclusion for patients who have been admitted for treatment of mental illness may also be met by a licensed psychologist who is listed or eligible to be listed in the national register of health services providers in psychology or who is certified by the American board of professional psychology and who has been granted hospital staff privileges to treat patients, in accordance with Section 50.36(3g)(b), Wis. Stats.

As noted above, BQA will distribute any official clarifications from HCFA as soon as they are received. For further information, please contact Beth Stellberg, Chief, Health Services Section, at (608) 266-3878 or Helen Brewster, ACSW, (608) 267-1443.

# Hospital Patient Rights

For the reasons set forth, Standard: Notice of rights. in the preamble, 42 CFR chapter IV, part 482 is amended as follows: PART 482--CONDITIONS OF PARTICIPATION FOR HOSPITALS 1. The authority citation for part 482, continues to read as follows: Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), unless otherwise noted. Subpart B--Administration 2. Section 482.13 is added to subpart B to read as follows:

**Sec. 482.13 Condition of participation: Patients' rights. A hospital must protect and promote each patient's rights.**

(a) *Standard: Notice of rights.*

(1) A hospital must inform each patient, or when appropriate, the patient's representative (as allowed under State law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible.

(2) The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance. The hospital's governing body must approve and be responsible for the effective operation of the grievance process and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee. The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control Peer Review Organization. At a minimum:

(i) The hospital must establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the hospital.

(ii) The grievance process must specify time frames for review of the grievance and the provision of a response.

(iii) In its resolution of the grievance, the hospital must provide the patient with written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.

(b)*Standard: Exercise of rights.*

(1) The patient has the right to participate in the development and implementation of his or her plan of care.

(2) The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.

(3) The patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with Sec. 489.100 of this part (Definition), Sec. 489.102 of this part (Requirements for providers), and Sec. 489.104 of this part (Effective dates).

(4) The patient has the right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital.

*(c ) Standard: Privacy and safety*.

(1) The patient has the right to personal privacy.
(2) The patient has the right to receive care in a safe setting.
(3) The patient has the right to be free from all forms of abuse or harassment.

*(d) Standard: Confidentiality of patient records*.

(1) The patient has the right to the confidentiality of his or her clinical records.
(2) The patient has the right to access information contained in his or her clinical records within a reasonable time frame. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its recordkeeping system permits.

*(e) Standard: Restraint for acute medical and surgical care*.

(1) The patient has the right to be free from restraints of any form that are not medically necessary or are used as a means of coercion, discipline, convenience, or retaliation by staff. The term “restraint” includes either a physical restraint or a drug that is being used as a restraint. A physical restraint is any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body. A drug used as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement and is not a standard treatment for the patient's medical or psychiatric condition.

(2) A restraint can only be used if needed to improve the patient's well-being and less restrictive interventions have been determined to be ineffective.

(3) The use of a restraint must be—
(i) Selected only when other less restrictive measures have been found to be ineffective to protect the patient or from harm others;
(ii) In accordance with the order of a physician or other licensed independent practitioner permitted by the State and hospital to order a restraint. This order must—
(A) Never be written as a standing or on an as needed basis (that is, PRN); and
(B) Be followed by consultation with the patient's treating physician, as soon as possible, if the restraint is not ordered by the patient's treating physician;
(iii) In accordance with a written modification to the patient's plan of care;
(iv) Implemented in the least restrictive manner possible;
(v) In accordance with safe and appropriate restraining techniques; and
(vi) Ended at the earliest possible time.

(4) The condition of the restrained patient must be continually assessed, monitored, and reevaluated.

(5) All staff who have direct patient contact must have ongoing education and training in the proper and safe use of restraints.

*(f) Standard: Seclusion and restraint for behavior managemen*t.

(1) The patient has the right to be free from seclusion and restraints, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. The term “restraint” includes either a physical restraint or a drug that is being used as a restraint. A physical restraint is any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body. A drug used as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement and is not a standard treatment for the patient's medical or psychiatric condition. Seclusion is the involuntary confinement of a person in a room or an area where the person is physically prevented from leaving.

(2) Seclusion or a restraint can only be used in emergency situations if needed to ensure the patient's physical safety and less restrictive interventions have been determined to be ineffective.

(3) The use of a restraint or seclusion must be—

(i) Selected only when less restrictive measures have been found to be ineffective to protect the patient or others from harm;

(ii) In accordance with the order of a physician or other licensed independent practitioner permitted by the State and hospital to order seclusion or restraint. The following requirements will be superseded by existing State laws that are more restrictive:

Orders for the use of seclusion or a restraint must never be written as a standing order or on an as needed basis (that is, PRN).

(A) The treating physician must be consulted as soon as possible, if the restraint or seclusion is not ordered by the patient's treating physician.

(B) A physician or other licensed independent practitioner must see and evaluate the need for restraint or seclusion within 1 hour after the initiation of this intervention.

(C) Each written order for a physical restraint or seclusion is limited to 4 hours for adults; 2 hours for children and adolescents ages 9 to 17; or 1 hour for patients under 9. The original order may only be renewed in accordance with these limits for up to a total of 24 hours. After the original order expires, a physician or licensed independent practitioner (if allowed under State law) must see and assess the patient before issuing a new order.

(iii) In accordance with a written modification to the patient's plan of care;

(iv) Implemented in the least restrictive manner possible;

(v) In accordance with safe appropriate restraining techniques; and

(vi) Ended at the earliest possible time.

(4) A restraint and seclusion may not be used simultaneously unless the patient is—

(i) Continually monitored face-to-face by an assigned staff member; or

(ii) Continually monitored by staff using both video and audio equipment. This monitoring must be in close proximity the patient.

(5) The condition of the patient who is in a restraint or in seclusion must continually be assessed, monitored, and reevaluated.

(6) All staff who have direct patient contact must have ongoing education and training in the proper and safe use of seclusion and restraint application and techniques and alternative methods for handling behavior, symptoms, and situations that traditionally have been treated through the use of restraints or seclusion

(7) The hospital must report to HCFA any death that occurs while a patient is restrained or in seclusion, or where it is reasonable to assume that a patient's death is a result of restraint or seclusion.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare Hospital Insurance; Program No. 93.778, Medical Assistance Program) Dated: May 24, 1999.Nancy-Ann Min DeParle,Administrator, Health Care Financing Administration. Approved: June 9, 1999.Donna E. Shalala,Secretary.[FR Doc. **99-16543 Filed 6-24-99**; 4:29 pm]